REMARKS

Of pending Claims 1-62, Claims 1, 2, 6-12, 24-26 and 30-62 have been rejected and Claims 3-5, 13-23 and 27-29 are objected to. The objections to Claims 2, 13, 14, and 30, as well as the claim rejections under 35 U.S.C. § 112 including Claims 8, 24-26, 30, 42, and 43 are corrected in the foregoing amendment. In addition, several minor amendments have been made to terms used in some of the claims to clarify the recitation and to comport the claim language more closely with the Detailed Description and the drawings. These amendments are made in Claims 1-5, 13, 27, 28, 30, and Claim 61.

Applicants appreciate the Examiner's findings of Allowable Subject Matter, including Claims 3-5, 13-23, and 27-29. Applicant respectfully submits that these claims do not need to be rewritten in view of the Remarks presented herein. Applicants also appreciate the allowability of Claims 42-43, 46-48, 53-56, and 60-62 if rewritten to overcome the rejections under 35 U.S.C. § 112, second paragraph. The foregoing amendment includes the necessary revisions. Applicants respectfully request that the respective objections and rejections be withdrawn and the affected claims allowed.

Applicants have made a minor amendment to Claim 30 to insert a comma after the second occurrence of the word "mode" in the fourth line of the claim to clarify that the element being recited in that clause is a "generator for generating pulsed RF signals in at least a first mode and a second mode." Applicants have further amended Claim 61 to more closely follow the language in the amended Claim 30 in which the element reciting a "means adapted to connect with the active probe for administering a liquid substance" is converted to a more specific recitation, that is: "an anesthetic metering device adapted to connect with the active probe for administering a liquid substance." Applicants respectfully submit that the foregoing minor amendments should clarify the recitations of the respective claims.

Several minor amendments to comport the language in Claims 1 - 3, and 27, 28 and 30 with the drawings and the written description are made. The word "attaching" in line 3 of Claim 1 and

lines 3 and 5 of Claim 2 is replaced with the word --placing--, as properly supported in the Detailed Description on page 14, line 12. A similar amendment is made to Claims 27, 28,and 30. The term "relative to" in Claim 1, line 4 is replaced with the word --against--, as properly supported in the Detailed Description at page 17, line 4. Inserted in line 13 of Claim 1 to comport the configuration of the "conductive spatulate blade" (see line 14) as illustrated in Figures 2, 4A, and 4B is the term --an elongated-- as clearly shown in these drawings. This term is also inserted in line 9 of Claim 30. Further, the phrase --active and dispersive locations-- is completed in Claim 2 at lines 4-5 and in Claim 3 at lines 9-10, in order to comport the recitation in these claims with their antecedent use in Claim 1. Applicants respectfully submit that these minor amendments are for purposes of clarifying the recitation of the invention to more closely comport with the support of the respective claims in the Detailed Description.

Claim 62 is cancelled because the recitation therein has been incorporated into independent Claim 30. A replacement sheet 3 of 7 of the drawings is filed concurrently herewith. The replacement sheet is identical with sheet 3 of 7 as filed except that the reference numbers 132, 134 for Figure 4B have been corrected.

Introduction:

It has been established by the Examiner that the inventions recited in Claims 1 and 30 are novel by the absence of any rejection under 35 U.S.C. § 102. However, these claims and others have been rejected under § 103(a) as being unpatentable in view of the combination of two or more patent references. Applicants respectfully submit that the inventions recited in Independent Claims 1 and 30 and the accompanying dependent claims set forth novel *and* non-obvious advances in the technology of pain reduction as applied to animal patients. The inventions provide a combination of steps and specially adopted techniques and equipment that is not taught by the prior art that has been cited in this case. Applicants respectfully suggest that it will be helpful to review the problems of treating pain in animal patients and the solutions provided in the method and apparatus recited respectively in Claims 1 and 30 and the claims depending therefrom.

Treating pain in animals, particularly large animals, presents difficulties to veterinarians that differentiate them from the therapies for treating pain in human patients. Although mammals in general share many anatomical and physiological similarities with humans, the anatomies and physiologies of animals differ in significant and sometimes subtle ways from that of human beings. For example, a *first* significant difference is that the skin of mammals is covered with hair. This presents a different set of problems when connecting electrical apparatus to the animal's skin or nervous system. *Second*, animals are adapted to different environments and their nervous systems have different sensitivities and respond in different ways to various conditions or stimuli they encounter. *Third*, their physical size is different and often requires different levels or different kinds of electrical signal energy to accomplish the desired result without harm to the patient. *Fourth*, animals cannot communicate in detail about the pain that they experience in the same way as human beings can. Thus, a veterinarian must use different methods of obtaining information about the pain that an animal may be experiencing in order to characterize the pain and to devise appropriate therapies for its reduction. Because of these and other differences, the apparatus and methods for employing electrical signals in the treatment of pain in human patients are not suitable without substantial modifications thereto - modifications that are unobvious in view of the prior art cited in the present case.

Accordingly, the following combination of features incorporated into the inventions recited in the independent Claims 1 and 30 have been conceived and developed to provide an effective solution to the problems of treating pain in animals, solutions heretofore not taught by the cited prior art alone or in combination. The Applicant's inventions include the following features:

(A) Configuring a first *modified* cannula for insertion through an incision in the skin (percutaneously) of the animal patient and placing it against a peripheral nerve and a second *modified* cannula for insertion through an incision a predetermined distance from the first modified cannula.

(B) Applying the combination of first and second distinct electrical signals connected across the first and second modified cannulas *in sequence*, (1) to verify the location of the target nerve to be treated, and (2) to stimulate the nerve in a particular way with radio frequency energy using a signal that comprises a modulated RF carrier wave.

(C) The addition of a spatulate blade of a particular shape to a *dorsal side* of the first and second RF cannulas to create a new configuration of a cannula.

(D) Including in the method for using the modified RF cannulas and electrical signals a preliminary step of measuring the electrical impedance between the active and dispersive cannulas in order to test the electrical connection between the instrument being used and the tissues of the patient.

(E) To include the step of monitoring the temperature of the tissues in the vicinity of the application of the radio frequency signals to avoid overheating the tissues that might result in ablation or destruction of the tissues in the vicinity of the cannulas.

The foregoing features are combined in a novel and unobvious combination to meet the heretofore unmet need in providing an effective treatment regime for reducing certain kinds of pain in animal patients.

A review of the prior art cited in the present case reveals the following distinct differences between the teachings of the prior art alone or in combination and the Applicant's invention as recited in Claims 1 and 30 and the accompanying dependent claims. *First*, none of the cited prior art references teaches a smooth, blunt ended cannula for insertion into an incision made for the purpose, i.e., percutanously or through the skin. *Second*, none of the cited prior art references teaches a cannula modified by attaching a spatulate blade to the dorsal side of the cannula to maintain optimum contact with a peripheral nerve in the patient. *Third*, none of the cited prior art references teaches the use of distinctly different first and second electrical signals in combination

according to respective predetermined first *and* second protocols, for (a) verifying the correct placement of the active and dispersive cannulas and (b) for supplying RF energy directly to the peripheral nerves appropriate to treatment of the injury experienced by the animal. *Fourth*, none of the cited prior art references teaches how to modify existing instruments used in treating human patients to adapt them specifically for use in treating large animal patients.

Claim Rejections Under 35 U.S.C. § 103:

CLAIMS 1-2, 6-12, AND 24-26

Claims 1-2, 6-12, and 24-26 are rejected under 35 U.S.C. § 103(a) as being unpatentable over *Silberstone, et al.*, in view of *Greengrass et al.* and further in view of *Smith*. The *Silberstone et al.* reference is alleged to disclose all of the recitations of Claim 1 except that the percutaneous probe includes an RF cannula having a conductive spatulate blade conformably attached to a dorsal side of the curved, blunt-ended tubular tip portion of the RF cannula. *Silberstone* also lacks any teaching about generating two distinct RF signals. In particular, *Silberstone* lacks the teaching of the first pulsed RF signal configured according to a first protocol . . . to verify the location of the peripheral nerve *and* the second pulsed (modulated carrier) RF signal configured according to the second protocol . . . to modify propagation of pain sensation in the peripheral nerve without ablation thereof. Further, a third deficiency in *Silberstone* is that Applicant's Claim 1 specifically describes *percutaneous* probes which are distinctly different from the transcutaneous probes used by *Silberstone,* which are applied to *the surface of* the patient's skin to transmit signals "into the skin" from one probe to another, thereby indirectly stimulating nerves of the patient. This is different than the use of percutaneous probes which are inserted into incisions through the skin of the patient to place the probes in contact with the peripheral nerve of the patient and administer the electrical energy directly to the peripheral nerve. These teachings, missing from the primary reference of *Silberstone* are not supplied by the teachings of the secondary references to *Greengrass* and *Smith* as will be explained.

Regarding *Greenglass*, it is alleged in the Detailed Action on page 5 that *"Greengrass* teaches as an RF cannula for positioning near a peripheral nerve . . . [and further] that it is well known in the art to combine a cannula with an electrical stimulator for nerves so that anesthetics can be administered [while] providing electrical stimulation through the electrodes in order to control pain." These assertions are incorrect because *Greengrass* according to his own disclosure teaches an epidural needle (col. 2, lines 13-18), for puncturing the skin and inserting it into a peripheral nerve for the purpose of aspirating blood from a vessel if one happened to be punctured during the procedure and for the purpose of injecting a local anesthetic prior to inserting an epidural needle for the continuous administration of anesthetic (col. 2, lines 43-51). In contrast, Applicants recite an RF cannula that has been *modified* with a spatulate blade attached to a *dorsal side* thereof to facilitate placing it *against* a peripheral nerve when *inserted through* an incision into the animal's tissue beneath the skin of the animal patient such that optimum electrical contact is provided between the surfaces of the modified RF cannula and the peripheral nerve. Thus, the structure and functions of the RF cannula recited by Applicants in the independent Claims 1 and 30 are distinctly different from the epidural needle described by *Greengrass*.

Significantly, *Greengrass* further does not teach the use of distinct and separately used first and second (active and dispersive) probes that are used at different locations on the patient nor does *Greengrass* teach the use of RF energy for the electrical stimulation applied to the active and dispersive probes as two separate signals to accomplish the separate purposes of the two separate signals as taught by the Applicant's claimed invention. Thus, according to the foregoing, *Greengrass* fails as secondary reference to supply several teachings absent in the *Silberstone* reference.

Even the addition of *Smith* to the combination cited by the Examiner is insufficient to teach the combination recited in Applicant's independent claims. *Smith* fails because, contrary to the assertions in the Detailed Action on page 5, the extension blade disclosed in *Smith* is attached to the end of a *wand*, not a dorsal side of a *cannula*, and the broad, spade-like extension is shaped much differently than the shape of the spatulate blade attached to the dorsal side of the curved, blunt-ended portion of the RF cannula recited in Applicant's Claims 1 and 30 and illustrated in Figures 4A and

4B of Applicant's Specification. This substantial difference in structure reflects the different conditions of use of Applicant's RF cannula within an incision against a peripheral nerve. Modifying the epidural needle of *Greengrass* with the spade-like blade as taught by *Smith* would result in a cannula that is inoperative for use in Applicant's invention (and therefore not suitable therewith).

Accordingly, even though three separate patents have been asserted in combination to teach Applicant's claimed inventions, the foregoing demonstrates that the substantial dissimilarities between the teachings in *Silberstone*, *Greengrass* and *Smith* cited in the Detailed Action and the structures and steps recited by Applicant's claims as amended do not resemble or provide the solution taught by Applicant's invention. Further, there is no suggestion or teaching in any of the cited references to combine one with the other without using Applicant's claim as a template, a procedure well known to be improper. Even using Applicant's claims as a template, the recited steps and elements have been shown herein above to not read on the cited prior art; indeed, this fact alone is sufficient to conclude that the asserted combinations in the Detailed Action teach away from the Applicant's inventions.

Applicants therefore respectfully submit that the cited combination of references is insufficient to render Claims 1 and 2, 6-12 and 24-26 as being unpatentable over the combination and respectfully requests the withdrawal of this rejection and full allowance of Claims 1-29 as amended. The Detailed Action separately addresses some of the dependent claims, namely, 7, 8, 9, 10, 11, 12 and 24-26. However, these are dependent claims based that include all of the limitations of the independent base Claim 1 as amended and which Applicants respectfully submit are allowable over the cited prior art as described above.

With respect to Claims 24, 25, and 26, these claims have been amended to recite a positive limitation and Applicants respectfully request the allowance thereof.

CLAIMS 30-41, 44, 45, 49-52 AND 57-59

Regarding Claims 30-41, 44, 45, 49-52 and 57-59 rejected under 35 U.S.C. § 103(a) as being unpatentable over *Silberstone* in view of the Applicant's disclosure and in further view of *Smith*, Applicants respectfully respond as follows. In the Detailed Action on pages 7 and 8, the rejection argument with respect to Claims 30, 44, 49, and 52 centers on a purported showing that the element "RF percutaneous probes . . . [comprising] an RF cannula having a conductive spatulate blade conformably attached along a longitudinal axis to a dorsal side of a curved, blunt-ended tubular tip portion of the RF cannula" is rendered obvious by the combination of "*Silberstone* in view of Applicant's disclosure and in further view of *Smith*." Applicants respectfully disagree for the following reasons.

First, the Examiner is correct to note at the top of page 8 of the Detailed Action that Silberstone "does not disclose that the [RF percutaneous] probes should be in the form of an RF cannula *with* a spatulate blade." Emphasis added.

Second, the portion of Applicant's disclosure selected by the Examiner as being a so-called "admission of prior art" is Applicant's Figure 3 and the accompanying Detailed Description on page 13. This material is clearly labeled "Prior Art," in order to clearly show how Applicant's novel modification illustrated in Figures 4A and 4B and described at pages 13 to 15 is distinguished from the prior art of Figure 3. This is necessary to comply with 35 U.S.C. § 112, first paragraph. The element of Applicant's claimed invention being attacked is not the RF cannula of Figure 3; rather, the Examiner should address the element as recited in the claim at issue, namely the RF percutaneous probe of Figure 4A and 4B. Applicant respectfully submits that the Examiner has overlooked the disclosure of Figure 4A and 4B, which clearly describes the RF percutaneous probe recited in Claim 30, only part of which is in the prior art. Applicant's RF percutaneous probe has been substantially changed into a novel combination by Applicant's modification. This modification to the prior art device is not taught by the references. Therefore, Applicants respectfully submit that the assertion that Applicant's disclosure is an "admission of prior art" is incorrect, it is not supported by the

evidence in the Specification, and it therefore carries no weight as a prior art reference relevant to Claim 30.

Third, the *Smith* reference is presented as purportedly teaching the modification Applicant has made to a prior art RF cannula. This too is incorrect because the spade-like extension to the wand of Smith is structurally incapable of the *percutaneous* use (insertion into a small incision through the patient's skin). The *percutaneous* use requires an elongated (as shown in Figures 4A and 4B) "spatulate blade *conformably attached along* a longitudinal axis to *a dorsal side* of [the] tubular tip portion of the RF cannula," (from Claim 30) as denoted by the italicized terms. This structure is distinguished from *Smith*, which lacks an *elongated* blade *conformably attached* to the *dorsal side* of the tip portion of the cannula. Thus, the broadly-shaped, spade-like extension blade of Smith, if substituted for Applicant's elongated spatulate blade attached to the side of the cannula, is improperly configured for insertion into a [small] incision through the patient's skin and is therefore incapable of use as the RF percutaneous probe recited in Applicant's Claim 30.

Thus, applicants respectfully submit that the foregoing evidence clearly shows that each one of these references asserted in combination as teaching the Applicant's invention recited in Claim 30 is deficient in the structure it is incorrectly asserted to disclose therefore, Applicants respectfully submit that Claim 30 as amended is not unpatentable as being obvious in view of the asserted combination of references and request the withdrawal of this rejection. Further, since Claims 31-41, 44, 45, 49-52, and 57-59 are dependent from base Claim 30, now believed to be allowable as amended and which contain all of the limitations of Claim 30, they are likewise patentable over the prior art of record. Applicants therefore respectfully request the full allowance of Claims 30-41, 44, 45, 49-52 and 57-59.

CLAIMS 31-41, 45, and 53

With regard to Claims 31 to 41, asserted by the Examiner to merely recite circumstances of intended use and not given patentable weight, Applicants respectfully submit that these claims are

in fact positive limitations which further limit the "generator for generating pulsed RF signals in at least a first mode and a second mode," which is the first element of independent apparatus Claim 30. Applicants further respectfully point out that, according to the duty of full disclosure set forth in 35 U.S.C. § 112, paragraph 2, "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his invention." Applicants therefore submit that the dependent Claims 31-41 fulfill this statutory requirement and are in full compliance with this provision of the patent statute. The withdrawal of this rejection and the full allowance of Claims 31-41 as amended (to satisfy other requirements made by the Examiner) is respectfully requested.

With regards to Claims 45 and 53, Applicants respectfully submit that each of these dependent claims set forth an additional limitation to the respective preceding Claim 44 or 52 and also ultimately to the independent Claim 30 and that such further limitation is fully in accordance with the requirement of 35 U.S.C. § 112, paragraph 2. Inasmuch as the independent Claim 30 as amended is now believed to be allowable over the cited prior art, Applicants respectfully submit that Claims 45 and 53 which now contain all of the limitations of the independent base Claim 30, are now likewise allowable and their allowance is requested. Similarly with regards to Claims 49 and 57 and also Claims 50, 51, 58 and 59 all of which recite further limitations to the preceding claims and ultimately the independent base Claim 30, the Applicants respectfully submit that each of these claims contain all of the limitations of the independent base Claim 30 as amended are now also allowable and their allowance is respectfully requested.

Included with this Amendment is a Request for an Extension of Time Within the Second Month since the date of response follows the expiration of the first three months following the mailing date of January 4, 2007, of the present Office Action. A check for the extension fee ($225.00) is enclosed.

If any additional fee is due for the continued prosecution of this application, please charge the same or credit any overpayment to Applicant's Deposit Account No. 50-2555 (Whitaker, Chalk, Swindle & Sawyer, LLP).

Respectfully submitted,

Date: May 11, 2007

Stephen S. Mosher
Reg. No. 33,974
Whitaker, Chalk, Swindle& Sawyer, LLP
301 Commerce St, Suite 3500
Fort Worth, Texas 76102
(817) 878-0549

ATTORNEY(S) FOR APPLICANT

R:\Stor\SSM\CLASSEN\AMEND.WPD